design ✦ specific

Executive Summary 510(k) Submission

Wheelchair Platform

Description	The device accommodates wheelchairs in a secure way, to enable them to be tilted backwards. Patient support is by an adjustable backrest with head support using an adjustable head cushion. The primary use is with patients who cannot be easily transferred from their chairs for such procedures as dentistry, Podiatry, Ear, nose and throat, maxio-facial work
Performance testing	Testing is carried out under the requirements as set out in BSEN1570:1999. This specifies the allowable stresses as 60% of yield stress at the design load and states that: • Full dynamic test at rated load recording operation times • 10 min delay under load to determine sink • Load increase by 10% and full dynamic test • Static test to 25% increase load

R. Fletcher
18.10.07

Substantial Equivalence Discussion 510(k) Submission

Wheelchair Platform

Predicate Devices

Convertible I-series Positioning and Transfer Chair
Barton Medical Corp.
5725 Hway 290 West
#103 Austin
TX 78735 8701
510(k) No. K071793

Electronic Positioning Chair
Medline Industries Inc
One Medline Place
JL 60060
510(k) No. K001937

Dental Tilting Ramp
TRICO Metal Products
Wyandotte Rd,
Willow Grove
Pennsylvania 19060
Manufacturers claim distribution prior to 1976

Rehabilitation Hospital Philadelphia
Introduction 1968, several sold.
Currently in use manufacturer unknown

Substantial equivalence is sought within the category 'Electronic Positioning Chair' (INO)

The Barton and Medline equipment under the heading is intended for use by patients who are NOT in wheelchairs. The Trico product is designed for the specific treatment of wheelchair patients. Equivalence is therefore sought, not on the grounds of visual appearance only, but on functionality. Patients in wheelchairs must be considered as being integral with their chairs, for it is not safe or beneficial for them to be removed

The Philadelphia Rehabilitation Hospital unit clearly predates the May 28th 1976 date and is the earliest version of equipment found so far. It has all the features and functions of a modern wheelchair recliner but uses the technology available at the period. At least two of these units are in current use and they were made available for sale.

The table, attached, shows that the Design Specific Standard Wheelchair Platform is equivalent in both function and technology to both the Medline and Barton positioning chairs. It shows that the Trico Wheelchair Tilting Ramp is similar in form and designed for exactly the same medical procedures. The Philadelphia Recliner has the same function and intended purpose as the Design Specific model, but takes a different design solution. The technology is appropriate to the period of the design.

Flowchart Analysis

Is the device new to the market?	Yes
Is new device to be compared to an existing device	Yes
Does new device have same indicated use statement?	Yes
Does the new device have the same technological characteristics (See table above)	Yes
Are descriptive characteristics enough to ensure equivalence	Yes

Substantial Equivalence been shown.

R. Fletcher
19.3.08

Characteristic	Medline Ind. Inc.	Barton Medical Corps	Trico Metal Ind.	Rehab. Hospital Philadelphia 1968	Design Specific Wheelchair Platform
Basic Platform Shape	Steel fabrication	Steel fabrication	Steel with cast iron base	Steel assembly	Steel fabrication
Drive mechanism	Electrical Linear Drive	Electrical Linear Drive	Electrical Linear Drive	Hydraulic	Electrical Linear Drive
Power source	Battery 12v	Battery 12v	110v supply ac	Manual	Battery 24v and Power supply delivering 24v
Backrest support	Normal chair back	Normal chair back	Uses wheelchair back with wheelchair locked in place	Uses wheelchair back with wheelchair locked in place	Pivots in and out adjustable by worm and wheel
Headrest	No separate headrest	Vertically adjustable headrest	Fixed headrest	Headrest attached to the wheelchair	Adjustable using a slotted arm with an adjustable headrest cushion for neck and head support.
Motions	Tilt only	Tilt and rise and fall	Tilt and rise	Tilt and rise	Tilt only
Command input	Fixed switches	Hand held controller	Fixed stalk with switch box	None	Fixed switches and radio remote control.
Foot crush protection	None	None	None	None	Pressure sensitive mat and guarding
Max. angle of tilt	Horizontal	Horizontal	Approx 25deg.	35deg. approx	45deg
Rated capacity	850lb	1000lb	Not known	Not known	594lb (BSEN1570:1999)
Proposed uses	". . .medical purposes. ."	" . .used to allow postural position . "	Wheelchair dentistry	Wheelchair Dentistry	Dental and medical applications
Static or mobile	Mobile on wheels	Mobile on wheels	Mobile on air cushion base	Static fixed base	Mobile on air cushion pads or ball castors

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Design Specific Ltd
% Ms. Dawn Edwards
1310 Templar Boulevard
Norfolk, Virginia 23518

Re: K073565
Trade Name: Standard Wheelchair Platform
Regulation Number: 21 CFR 890.3110
Regulation Names: Electric positioning chair
Regulatory Class: II
Product Code: INO
Dated: October 21, 2008
Received: October 31, 2008

FEB - 6 2009

Dear Ms. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K073565

Device Name: standard Wheelchair Platform

Indications For Use:

Patients in wheelchairs present problems to clinicians who need to treat them and the patients themselves can be seriously disadvantaged by their situation. This is particularly true of dental treatment. To be treated the dentist would need to bend around the patient in the wheelchair, that cusses back pain and sometimes injury. An alternate approach is to transfer the patient to a conventional chair by slings and hoists or other approaches, all of which hold significant health and safety risks.

The wheelchair platform offers a safe environment for both clinician and patient. The wheelchair is moved onto the platform up against a back wall support and the wheelchair and patient are then supported by a backrest and a head support. The platform is reclined, and possibly raised and lowered, to present the patient in the best position for treatment.

Prescription Use ___N__ AND/OR Over-The-Counter Use ——N——,
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS) LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division S...

Division of General, Restorative, and Neurological Devices

K073565